bespak

Bespak, Inc.
2450 Laura Duncan Road
Apex, NC 27523

Telephone 919 387 0112
Sales Dept Fax: 919 387 1241
Purchasing Fax: 919 387 0115
Engineering Fax: 919 387 0116

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Dockets Management Branch
Docket Number 03P-0029
U.S. Food and Drug Administration
Room I-23
12420 Parklawn Drive
Rockville, MD 20857

Re: **Comments Regarding Citizen Petition Submitted by the U.S. Stakeholders Group on MDI Transition (Docket Number 03P-0029)**

As a responsible corporation, Bespak wholly supports the transition from ozone-depleting substances ("ODS") to non-ozone-depleting substances. Over the last 15 years, Bespak has led the transition to non-ODS substances by making very significant investments to provide its customers with next generation aerosol metering valves and actuators ("MDI Components") suitable for HFA products.

Bespak is aware of the importance of albuterol metered dose inhalers ("MDIs") to asthma patients and is writing this letter in its efforts to ensure that any decision to remove albuterol from the list of essential uses for ODS be made on the basis of the most recent facts. Therefore, Bespak hereby submits comments to the April 1, 2004 letter to the FDA from the U.S. Stakeholders Group on MDI Transition, which requests that the FDA promptly issue a notice of proposed rulemaking to remove albuterol from the list of essential uses for ODS.

Bespak assures the FDA that it has the ongoing capacity to supply MDI components necessary for ongoing use of CFC MDIs, including albuterol MDIs, and is committed to maintaining supply as long as patient requirements are sufficient to warrant continued production.

Bespak has been supplying the global MDI industry with MDI components for over 30 years. Currently, our range of metering valves and actuators are approved throughout the world on numerous MDI products including both CFC and HFA based formulations. Specifically, in the U.S., Bespak is the leading supplier of MDI components for CFC albuterol and is well aware of the importance to the industry and to the patients of maintaining a constant supply of this life saving medication. Additionally, Bespak is extremely active with the transition, as there are a number of products under development or pending approval with FDA that utilize Bespak MDI components.

The April 1, 2004 letter claims that patient health is at risk due to uncertainties about long-term, reliable supply of MDI components. On the contrary, Bespak is working very closely with the pharmaceutical industry and has taken the necessary steps to ensure an uninterrupted supply of CFC components well into the next decade.

Bespak will continue to work with all MDI manufacturers to ensure the availability of adequate CFC MDI component supplies irrespective of the transition. It is Bespak's intent to allay any concerns FDA might have regarding patient risk as it relates to the of supply MDI components. It is our hope that this clarified position will allow thorough consideration for a reasonable transition plan.

We appreciate the opportunity to make our views known to FDA. Should you have any questions or require further information on this matter, please do not hesitate to contact me.

Sincerely,

Mark Throdahl
CEO Bespak plc

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